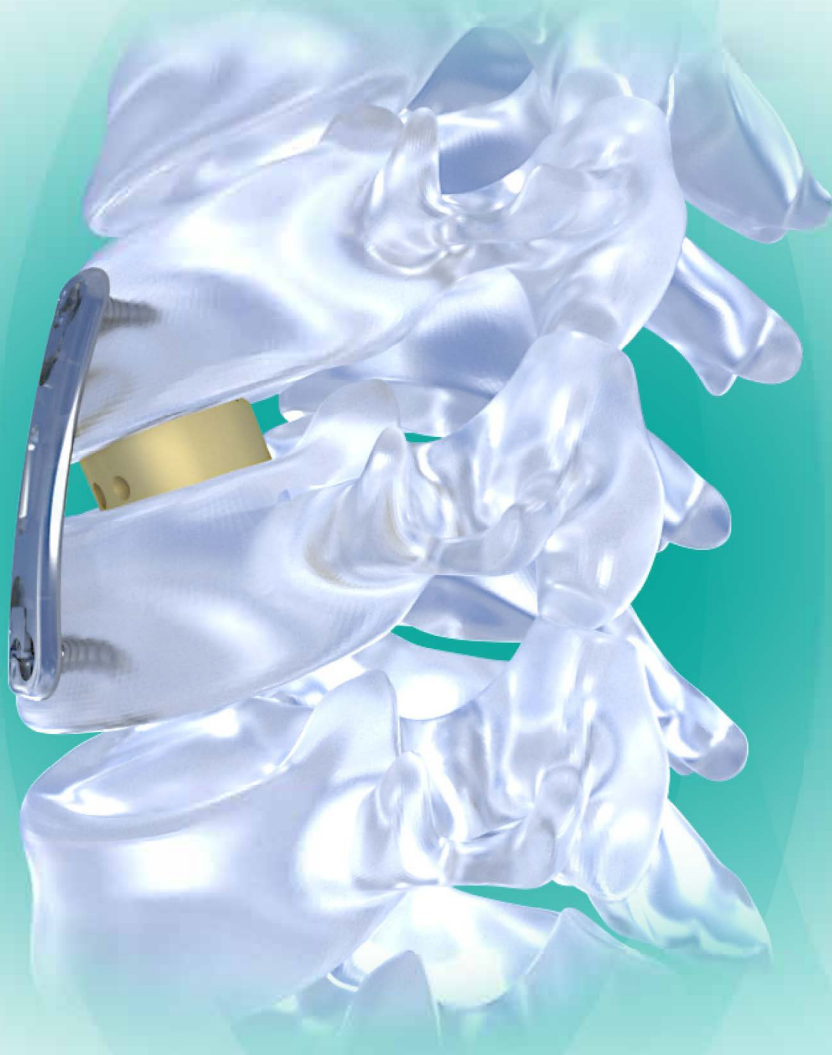


PEEK Anterior Cervical Cage

Technical Manual





Why Choose Fule? Fule advantage

- Beijing Fule is a national high-tech enterprise integrating R&D, production and sales of medical equipment, and has a production line of fully intelligent processing equipment.
- The academician expert studio was established to help Fule improve its research and development capabilities, and further deepen the cooperation of production-academy-research; it was approved as a post-doctoral research station.
- The hardware facilities are complete, the R&D team is excellent, and the clinical experts work closely with more than one hundred domestic and foreign patents.
- Based on the agent cooperation model, it has established a nationwide sales and service network, and its products are supplied to nearly a thousand tertiary hospitals across the country and exported to more than 20 overseas countries.



Contents

Products Advantage.....	01
IFU	03
Surgical Technical	04
Products Information.....	13
Instruments	14

Products Advantage

- Wedge and Arc shape can be selected according to the condition of vertebral endplate.

- The larger contact area between the upper and lower surfaces reduces the incidence of end plate settlement.

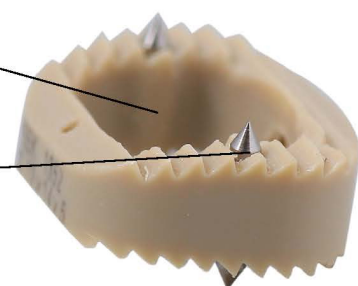
- Dentate protrusions on the upper and lower surfaces to reduce the incidence of displacement after implantation.

- Self-stable structure design, increase the stability of the cage.

- Large space for bone grafting is conducive to bone fusion.

- Preset developing needle for postoperative X - ray monitoring.

- PEEK material promotes bone fusion, and the light transmission is beneficial to observe the bone graft fusion after surgery.



Products Advantage

- Cage Trail



- Distractor



- Insertor



IFU

● 【Indications】

1. Single-level cervical spondylotic myelopathy or radiculopathy, which cannot be relieved by non-surgical treatment, and the symptoms and signs are gradually aggravated.
2. Cervical spondylotic myelopathy, severe in a short period of time, should be operated as soon as possible.
3. Sudden cervical spondylosis or induced by trauma, resulting in quadriplegia.
4. Patients with severe or progressive cervical disc herniation that cannot be alleviated by non-surgical treatment.

● 【Contraindications】

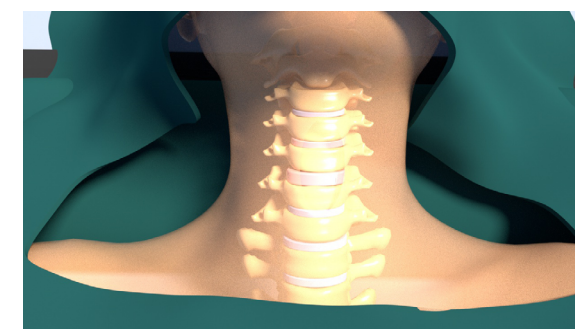
1. Cervical vertebra fracture;
2. Cervical tumor;
3. Severe osteoporosis;
4. Severe instability;
5. Spinal cord infection;

Surgical Technical

【Step 1】

Patient position adjustment

- The patient lies supine on a fluoroscopic operating table. Make sure the patient's neck is in a neutral sagittal position and use a cervical pad.



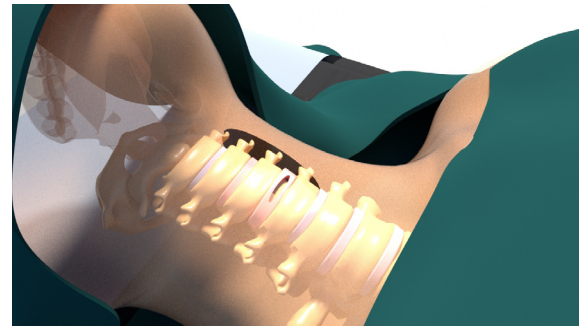
When performing C5-C6 segment surgery, ensure that the shoulder does not block intraoperative fluoroscopy.

- An anterolateral cervical incision is made to expose the affected cervical disc and adjacent vertebrae.

Surgical Technical

【Step 2】 Deal with nucleus pulposus

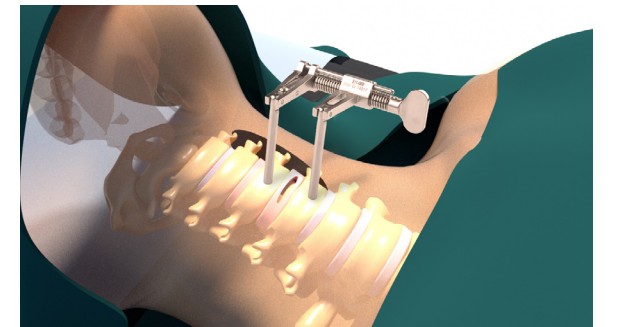
- A 15mm wide window was cut on the anterior ligament and annulus fibrosus in front of the intervertebral disc, and the nucleus pulposus was cleaned through the window.
- It should be noted that the anterior ligament and annular fibrous tissue should be preserved as much as possible during the fenestration process, which has a good stabilizing effect on the Cage after implantation.



Surgical Technical

【Step 3】 Vertebral body distraction

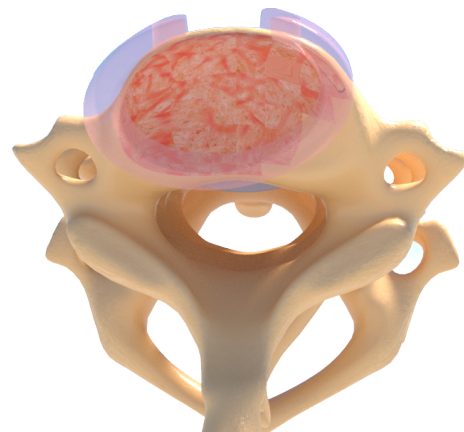
- The pins were held with pin holder, and the two pins were respectively implanted into the anterior edge of the vertebral body.
- Remove the pin holder and place the cervical distractor into the step of the pin to spread the affected vertebra to restore normal intervertebral height.
- A distraction operation can be performed to estimate whether satisfactory endplate treatment can be performed in the intervertebral space.



Surgical Technical

【Step 4】 Endplate treatment

- Remove cartilage from the surface of the disc and vertebral endplate until blood oozes out.
- The ultimate purpose of the end plate is to protect the natural appearance of the hard subchondral bone layer and vertebral body and reduce the probability of subsidence. Proper handling is also important for blood supply to grafted bone.



Surgical Technical

【Step 5】 Choose implant size and shape

- According to the preoperative measurement of the disc height and the intraoperative appearance of the endplate, the appropriate height of the arc or wedge cage trail was selected.

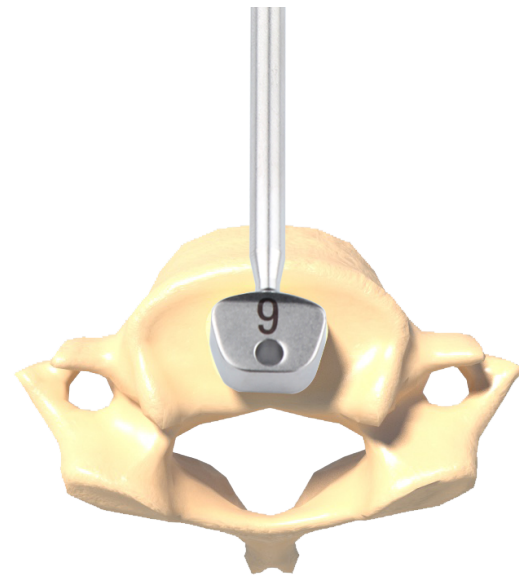
Note: Arc Cage is suitable for healthy end plate, ensure that the arc protrusion is upward to the head during installation, wedge Cage is suitable for degenerative end plate, no positive or negative difference.



Surgical Technical

【Step 6】 Cage trial testing

- The cage trial was implanted into the intervertebral space, and its position and matching degree with the upper and lower endplates were examined by fluoroscopy. If the first test model was not closely matched with the upper and lower endplates, an additional number should be added for another test.
- Due to the tension of the ligament and the annulus fibrous, it is necessary to ensure the intervertebral height as large as possible, and to ensure the implantation depth by referring to the scale on the head of the wrench (holder). The leading edge of Cage is 2mm from the anterior edge of the vertebral body.



Surgical Technical

【Step 7】 Cage choice

- According to the size of the cage trial, the Cage is locked on the cage insertor.
Note that when the Cage is locked on the cage insertor, the end face of the Cage should be corresponding to the end face of the cage insertor.
- The arrow direction on the cage is pointing in the direction of the head.



Surgical Technical

【Step 8】 Fill the bone graft

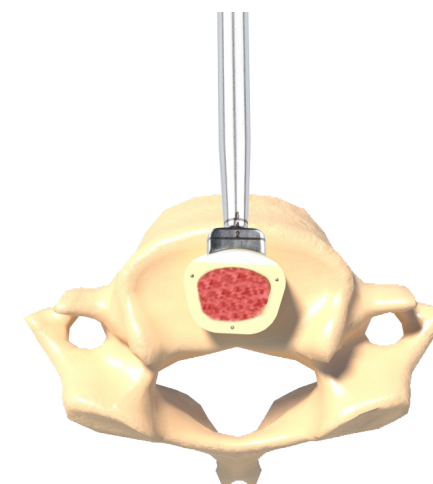
- The Cage was placed in the packing block, and the autologous bone fragments or artificial bones prepared in advance were placed in the Cage's round hole, and compacted with the impactor until the autologous bone or artificial bone was full.



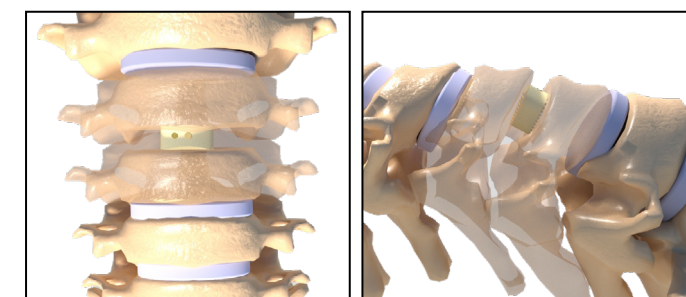
Surgical Technical

【Step 9】 Cage implantation

- With the vertebral body distracted, the Cage with bone graft was implanted into the treated intervertebral space (9a).
- If necessary, gently knock with the impactor until the cage is placed at an appropriate depth. Pay attention to ensure the best placement position, and the center line should be aligned with the center line of the vertebral body.
- After implantation, fluoroscopy was performed to check the position accuracy of the cage and the cervical distractor was removed (9b).



9a



9b

Products Information



● 【PEEK Anterior Cervical Cage, Arc】

Size	Angle	Thickness	Length	Width	Code
12×14.5×5	8°	5	12	14	1109012005
12×14.5×6	8°	6	12	14	1109012006
12×14.5×7	8°	7	12	14	1109012007
12×14.5×8	8°	8	12	14	1109012008
12×14.5×9	8°	9	12	14	1109012009



● 【PEEK Anterior Cervical Cage, Wedge】

Size	Angle	Thickness	Length	Width	Code
12×14.5×4	4°	4	12	14	1110012004
12×14.5×5	4°	5	12	14	1110012005
12×14.5×6	4°	6	12	14	1110012006
12×14.5×7	4°	7	12	14	1110012007
12×14.5×8	4°	8	12	14	1110012008
12×14.5×9	4°	9	12	14	1110012009

Instruments



● 311-010
Cage Insertor



● 311-020
Packing Block



● 311-030
Impactor



● 311-140~311-144
Cage Trail (Arc, 5/6/7/8/9)



● 311-145~311-150
Cage Trail (Wedge, 4/5/6/7/8/9)



● 201-010
Cervical Distractor



● 311-180
Pin Holder



● 311-170
Pin

Instruments



● 313-170
Handle for Cage Trail